

Bayer



Bayer AG
Investor Relations
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Investor News

Treatment of acute peripheral arterial occlusion:

Nuvelo Product Candidate Alfimeprase Receives FDA Fast Track Status

Bayer HealthCare To Commercialize Alfimeprase in All Territories Outside the U.S.

Leverkusen / January 23, 2006 – Nuvelo Inc. (Nasdaq: NUVO) today announced that it has been granted fast track designation by the U.S. Food and Drug Administration (FDA) for its lead product candidate, alfimeprase, for the treatment of acute peripheral arterial occlusion (PAO), or “leg attack.” Bayer HealthCare recently announced that it has entered into a collaboration with Nuvelo Inc. for the global development and commercialization of alfimeprase.

Fast track designation, which was mandated by the FDA Modernization Act of 1997, can potentially facilitate development and expedited review of Biologics License Applications (BLA). Fast track designation is reserved for new drugs that demonstrate the potential to address an unmet medical need and are intended for the treatment of a serious or life-threatening condition.

Alfimeprase is currently being studied in phase III clinical trials for the potential treatment of acute PAO and catheter occlusion (CO), and may have utility in a wide range of additional thrombotic-related conditions such as stroke, deep venous thrombosis (DVT) and myocardial infarction. Collectively, these disorders are among the most common causes of death and morbidity in the Western world.

“We recently received a special protocol assessment agreement for NAPA-3, our second pivotal phase III trial in acute PAO. Fast track designation represents a further step in the achievement of our regulatory strategy for alfimeprase,” said Ted W. Love,

M.D., chairman and chief executive officer of Nuvelo. "With a more defined regulatory path, a phase III program continuing to progress and a strong global commercialization partner in Bayer HealthCare AG, we believe we are progressing toward our goal of bringing this therapy to individuals suffering from clot related disorders."

Alfimeprase in Clinical Trials

Alfimeprase is being studied in an ongoing phase III program known as the NAPA (Novel Arterial Perfusion with Alfimeprase) program, for the treatment of acute PAO. The program consists of two overlapping randomized, double-blind, multi-national trials comparing 0.3 mg/kg of alfimeprase versus placebo in a total of 600 patients. The primary endpoint in both trials is avoidance of open vascular surgery within 30 days of treatment. Open vascular surgery includes procedures such as surgical embolectomy, peripheral arterial bypass graft surgery and amputation, but does not include catheter-based procedures such as percutaneous angioplasty or stenting. A variety of secondary endpoints are also being evaluated, including safety endpoints such as the incidence of bleeding, and pharmacoeconomic endpoints such as length of hospital and intensive care unit (ICU) stay. The first trial in this program, NAPA-2, is expected to complete enrollment in the second half of 2006 and the second trial, NAPA-3, is expected to begin enrollment in early 2006.

Alfimeprase is also being studied in an ongoing phase III clinical program known as the SONOMA (Speedy Opening of Non-functional and Occluded catheters with Mini-dose Alfimeprase) program, for the treatment of CO. The program consists of two overlapping, multi-national trials. The first trial, SONOMA-2 is an efficacy study comparing 3 mg of alfimeprase versus placebo in 300 patients with occluded central venous catheters, evaluating restoration of function to the catheters at 15 minutes. SONOMA-2 is expected to complete enrollment in the second half of 2006. The second trial, SONOMA-3, will be an open label, single-arm trial evaluating alfimeprase alone in 800 patients. This study's primary endpoint is safety; however efficacy will also be evaluated. SONOMA-3 is expected to begin enrollment in the first half of 2006.

About Leg Attack

Acute PAO, or "leg attack," occurs when arterial blood flow to a lower limb is blocked by a clot. Affecting more than 100,000 people in the United States each year, acute PAO is the result of underlying peripheral arterial disease, in which chronic fatty

plaque buildup restricts blood flow and is then complicated by the formation of an acute clot. If blood flow is not restored, leg attack can lead to permanent nerve and muscle damage, gangrene, and in the most severe cases, amputation and death.

Currently, because there are no FDA-approved thrombolytic therapies available to treat acute PAO, off-label use of plasminogen activators often occurs. As noted in published studies, plasminogen activators may require a prolonged infusion averaging 24 to 36 hours in patients with acute PAO, carry the risk of significant bleeding complications and typically require admission to the ICU for the duration of the infusion.

About Alfimeprase

Alfimeprase is an enzyme produced by recombinant DNA technology that rapidly resolves blood clots through a unique mechanism of action; it directly degrades fibrin, a protein that provides the scaffolding for blood clots. In clinical studies to date, alfimeprase has been shown to have the ability to resolve peripheral arterial (e.g. leg) clots within four hours of initiation of dosing and to clear occluded catheters in 15 minutes or less. In addition, its lytic activity is localized to the site of delivery due to its rapid inhibition by alpha-2 macroglobulin, a naturally occurring protein in the blood, as soon as it moves away from the clot and into the general circulation. This clearance mechanism helps focus the thrombolytic activity to the site of delivery and, in clinical testing, appears to minimize bleeding side effects.

Bayer HealthCare

Bayer HealthCare, a subsidiary of Bayer AG, is one of the world's leading, innovative companies in the health care and medical products industry based in Leverkusen/Germany. In 2004, the Bayer HealthCare subgroup generated sales amounting to some 8.5 billion Euro. Bayer HealthCare employed 35,300 people worldwide in 2004.

The company combines the global activities of the divisions Animal Health, Consumer Care, Diabetes Care, Diagnostics and Pharmaceuticals. Since January 1, 2006 the new Pharmaceutical Division consists of the former Biological Products and Pharmaceutical Division and now comprises three business units: Hematology/Cardiology, Oncology and Primary Care.

Bayer HealthCare's aim is to discover and manufacture innovative products that will improve human and animal health worldwide. The products enhance well-being and quality of life by diagnosing, preventing and treating diseases.

Leverkusen, January, 23, 2006

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Bayer Clinical Trials on Trasylol Not Consistent with New England Journal of Medicine (NEJM) Study

Leverkusen / January 26, 2006 – In response to press reports regarding a study appearing today in the New England Journal of Medicine (NEJM) Bayer HealthCare said “The study conclusions published today by Mangano et al. are not consistent with the more than 15 years of clinical trial data and experience Bayer has amassed on Trasylol.”

Bayer has studied aprotinin in a series of prospective, randomized, double-blind, placebo-controlled clinical trials encompassing almost 6,500 open heart surgery patients worldwide (aprotinin N = 3817, placebo N= 2682). This study population is larger than the patient population in the study by Mangano et al. Bayer’s randomized trials examined results from 3,817 aprotinin patients in comparison to the 1,295 aprotinin patients in the Mangano et al. observational study. In these trials Bayer did not see the increases in renal failure, myocardial infarction, congestive heart failure and stroke or encephalopathy associated with use of aprotinin in patients undergoing coronary-artery surgery that were reported in Mangano et al observational study.

Bayer is in the process of contacting the study authors to discuss the details of their data, study methodology, and analysis. We have also alerted regulatory authorities about this publication. Patient safety is Bayer’s highest priority and, as always we take publications of this nature very seriously. Bayer believes that Trasylol is a safe and effective treatment when used in accordance with the product labeling.

About Trasylol

Trasylol, a broad-spectrum proteinase inhibitor, modulates the systemic inflammatory response associated with cardiopulmonary bypass (CPB) in the course of CABG surgery. Approved by the FDA in 1993, Trasylol is the only product indicated for

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